

REMARKS

Applicant respectfully requests consideration of the following remarks. Claims 1, 2, 8-23, 88, 240, and 241 are pending.

Rejection under 35 U.S.C. §103(a)

The Examiner rejected claims 1-2, 8-23, 240 and 241 under 35 USC §103(a) as being unpatentable over Tian (Tian et al., "Polymer Preprints" (2002) 43(2); 719-720) in view of Uhrich (WO 03/005959).

This rejection is respectfully traversed. The Supreme Court set out the analysis for patentability under 35 USC 103(a): the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background the obviousness or nonobviousness of the subject matter is determined (*see, e.g., Graham v. John Deere Co.*, 383 U.S. 1 (1966) and *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (2007)).

The Examiner states that Applicants' arguments have been fully considered but are not persuasive.

The Examiner first notes that: "Applicants argue that Tian does not specifically disclose the use of the disclosed compounds for LDL removal or treatment of atherosclerosis (response, p. 6)." In fact, the Examiner has conceded exactly this point in the initial Office Action in this case and relies on Uhrich to make up for this deficiency. (See Office Action, mailed February 19, 2009, paragraph 2. bridging pages 6-7).

The Examiner then states: "In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986)." This quotation does not mean that it is always improper to discuss references individually. For example, it is permissible to perform analysis of individual references cited in an obviousness rejection to show that all one or more elements of a claim are not present or to show one or more reasons why the cited references may not be combined to sustain an obviousness rejection. Indeed, the Applicants have specifically argued that Uhrich *does not* provide the teaching and

suggestion the use of the compounds claimed in present application for the removal of LDL and/or the treatment of atherosclerosis *and*, in conjunction with the Examiner's concession that Tian does not disclose the use of the disclosed compounds for LDL removal or treatment of atherosclerosis, the rejection should be withdrawn.

The Examiner states: "It is noted that the molecules of Tian are encompassed by the disclosure of Uhrich as stated in the prior Office Action. The amphiphilic molecules, which are attached to the small core emphasized by applicants, can be the same molecules as disclosed by Tian, according to Uhrich's disclosure. Applicants have provided absolutely no evidence to suggest or demonstrate that adding a small polyfunctional core to Tian's (much larger) molecules would change the activity of the appended molecules, particularly given Tian's direct teaching that the nonpolymerized molecules function in the same way."

Applicants disagree with the need for such evidence. In the prior response, Applicants did point out that the *intermediate* molecules of Tian are covalently linked in Uhrich by a core molecule. One of skill in the art would readily appreciate that such covalent linkage would change the conformation and behavior in solution of the Tian molecules. In fact, Uhrich points out that it is the core that "...forms a hydrophobic microenvironment that encapsulates small hydrophobic molecules." (Uhrich at page 34, lines 21-22). Moreover, Uhrich describes the micelles disclosed therein as "unimolecular" micelles (see e.g. Uhrich at page 34, line 13) Uhrich goes on to state that: "Unlike conventional micelles, however, the polymeric micelles of the present invention are thermodynamically stable because of the covalent linkages between the polymer arms. The ability to encapsulate small molecules, the enhanced solubility and the lack of aggregation characterize the usefulness of these polymers as drug delivery systems." (Uhrich, page 34, lines 23-27). Therefore, Uhrich distinguishes the behavior of the molecules disclosed therein from the intermediate molecules of Tian.

The Examiner continues: "In order for applicants' argument to be persuasive, applicants must demonstrate that the functional part (i.e. the LDL sequestering portion) of the molecule is the small polyfunctional core, which applicants have not done. In fact, Tian's teachings suggest otherwise. There is nothing to suggest that the micelles of Tian would be unsuitable for the same uses as the polymerized versions those of Uhrich. Since Tian directly teaches that the non-polymerized molecules form micelles capable of transporting lipophilic compounds just like those of Uhrich), a skilled artisan would understand that it is the amphiphilic portions (i.e. Tian's

molecules) themselves that are responsible for the sequestration of the hydrophobic compounds (i.e. per Tian's Scheme 1) rather than a small polyfunctional core that is present merely to link several of the amphiphilic compounds together. One would clearly have a reasonable expectation of success in using Tian's molecules for the same purposes as those described for the polymerized versions of Uhrich. Applicants provide no evidence of any kind to support their assertion that Uhrich's molecules are not simply polymerized versions of Tian's molecules.”

Applicants disagree. The requirement to demonstrate that the functional part (i.e. the LDL sequestering portion) of the molecule is the small polyfunctional core appears to be arbitrary. Applicants only need to show why the combination of Uhrich and Tian is improper. Moreover, even if it were the case that there is nothing to suggest that the micelles of Tian would be unsuitable for the same uses as the polymerized versions those of Uhrich, that is not the standard for a proper combination with Tian with Uhrich. As shown above, Uhrich points out the differences from Tian in structure both in the molecular structure and the structure of the micelles formed.

It is submitted that the combination of Tian with Uhrich remains improper for sustaining the rejection. Accordingly, reconsideration and withdrawal of the rejection are requested.

CONCLUSION

The Examiner is invited to contact Applicant's Representative at the below-listed telephone number if there are any questions regarding this Response or if prosecution of this application may be assisted thereby. If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 50-3503. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extension fees to Deposit Account 50-3503.

Respectfully submitted,

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By their Representatives,

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By: 

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